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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,651	07/08/2002	Elisabeth Csoregi	50159-026	5727

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/22/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,651

Applicant(s)

CSOREGI ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: |

Status of the Claims

The response with amendments and IDS filed 12 May 2003 has been received and entered. Claims 13-22 have now been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Jon P. Weber, Ph.D.

Specification

The amendment filed 12 May 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In Table I, both changes are said to obvious typographical errors by comparison to other values on the table. However it is not seen how the value 134 ± 0.03 could become 1.03 ± 0.03 . No evidence is provided how 0.70 becomes 0.07; the other values are not significantly different. Nothing about the other values on the table renders these obvious typographical errors.

Applicant is required to cancel the new matter in the reply to this Office Action, or other appropriate action.

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The disclosure stands objected to because of the following informalities:

At page 12 “metyldiater” has been changed to “methyldiater” which is just as confusing. From reading the paragraph as a whole, it would appear that what may have been intended is “mediator”.

Appropriate correction is required.

Claim Objections

New claim 13 is objected to because of the following informalities: Claim 13 recites “determination of freshness biomarkers in the form of biogenic amines” which is not much better than original claim 1. It is suggested that the more correct and clear “determination of biogenic amines as freshness markers” be used instead. Appropriate correction is required.

Claim 17 recites “on to” which should be “onto”.

Claim 17 recites that the Type II enzyme system is added “on the top” of the electrode which should probably be “on top”. Actually it might be better to indicate that both Type II and Type III are coated on the surface of the electrode, which is more correct. “Top” could be confused with a vertical location.

Claim Rejections - 35 USC § 112

Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) comparison of the electrical output to some standard curve for amines or for histamine, 2) establishing a relationship between the electrical output and

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freshness or for histamine. In point of fact, the sensor detects biogenic amines, generically. No evidence is presented that histamine can be distinguished from other biogenic amines, or necessarily that biogenic amines provide a one-to-one mapping to freshness.

Claim Rejections - 35 USC § 103

Claims 13-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 199323748) in view of Ohashi et al. (US 5,565,329).

It is argued that the enzymes in Heller et al. are not coupled as required by the instant claims because they are isolated from each other.

In Heller et al., the two enzymes are kept in separate layers. This does not mean that the reactions are not coupled. In fact, the enzyme reactions are selected so that they can be coupled. The first enzyme on the electrode generates peroxide so that the main enzyme, peroxidase, will have a substrate to act upon. Sarcosine oxidase is a specific example of a suitable coupling first enzyme (see paragraph bridging pages 15-16).

It is argued that the Office action admits that the amine oxidase from grass pea is not provided by either Heller et al. or Ohashi et al. as required by the claim. It is argued that although the Office action takes the position that enzymes with the same EC can be substituted for each other, it is urged that the grass pea enzyme is more sensitive and specific than the *Aspergillus niger* enzyme used by Ohashi et al. It is also argued that the grass pea amino oxidase uses a topaquinone co-factor unlike other amine oxidases.

According to Expasy (<http://www.expasy.org/cgi-bin/nicezyme.pl?1.4.3.6>), most all of the amine oxidases have copper and topaquinone (2,4,5-hydroxyphenylalanine quinone) as their

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cofactors. It is not unique to grass pea copper-amine oxidase. This confirmed by Brenda (http://www.brenda.uni-koeln.de/php/result_flat.php3?ecno=1.4.3.6). The enzymes from a variety of sources are known in the art as shown by Brenda. The grass pea, *Lathyrus sativus*, is in the same genus as *Lathyrus cicera*, for which the amine oxidase has been partially purified and studied (Cogoni et al., 1989).

There does not appear to be any advantage in the selection of one amine oxidase over another for the method instantly claimed. Further the disclosure does not support the argument in the response that the enzyme from grass pea is more selective and sensitive than the enzyme from *Aspergillus*. While it is clear from the information at Brenda, that the enzyme from each species will have varying values for K_m , there is no evidence in the disclosure or the art that supports the generic argument of the response. What the instant disclosure actually says is not that the enzyme from *Aspergillus* has less selectivity and sensitivity than the enzyme from grass pea, but rather that the method or "approach is not very selective and sensitive" (page 2, lines 10-11), referring to the dissolved oxygen measurement being made in Ohashi et al. There is no advantage disclosed in the specification that the grass pea amine oxidase has over any other amine oxidase for the claimed method.

Applicant's arguments filed 12 May 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

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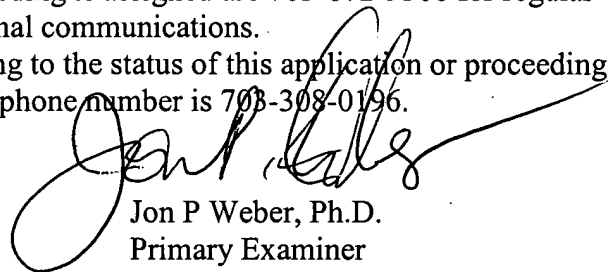
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
July 21, 2003